K063476

JAN 2 2 2007

510(k) SUMMARY

Submitter	Breas Medical AB Företagsvagen 1 SE 435 33 Molnlycke Sweden
Contact Person	Karl-Johan Holm Quality Assurance and Regulatory Affairs Manager Phone: +46 31 868830 Fax: +46 31 868810
Summary Date	April 11, 2006
Name of Device	Breas iSleep 20i System
Common Name	CPAP system
Classification Name	Non-continuous ventilator (21 CFR 868.5905)
Product Code	BZD
Predicate Device	Breas PV10i (K030985)

Device Description:

The iSleep 20i system is a CPAP system that provides a continuous positive airway pressure. This can prevent the user's upper airways from collapsing and therefore avoid breathing problems associated with collapse and obstruction.

In the treatment of chronic respiratory failure, positive airway pressure ventilation is well established and common practice as a mean to assure sufficient gas exchange. There are a number of devices legally marketed in the United States for this application.

The iSleep 20i system can be used in clinical settings (e.g., hospitals, sleep laboratories, sub-acute care institutions) and home environments.

It must always be prescribed by a licensed physician.

It is not intended for life support applications or for transport of critical care patients.

The therapy delivered by the Breas iSleep 20i CPAP System can be either:

1) Self-adjusting in response to variations in patient breathing patterns (CPAP "i" mode), or
2) Set to a constant pressure level (constant CPAP mode).

The iSleep 20i airflow is delivered via a single lumen outlet tube that may be connected to various non-invasive patient interfaces, such as nasal masks. To minimize CO_2 rebreathing, masks or other interfaces permitting a leak flow of at least 12 liters/minute at the output pressure setting of 4 cmH_20 are recommended.

The iSleep 20i systems have an auto-switching power supply that facilitates use in conjunction with international travel (100 – 240 VAC). It can also be used with an external 12.5/ 24 VDC power source when AC mains line voltage is not available.

The outer dimensions of the iSleep 20i housing is 6.8 x 6.8 x 8.2 inches, and the device weighs 3.1 pounds including empty humidifier.

Intended Use:

The iSleep20i is intended for non-invasive use.

The iSleep20i shall only be used by patients with spontaneous breathing.

The CPAP function is intended to deliver continuous positive airway pressure therapy for the treatment of obstructive sleep apnea in adults (who weigh more than 30 kg).

The iSleep 20i is intended to be operated by trained users and qualified personnel.

Comparison of Use and Technological Characteristics:

The iSleep 20i system can be used in clinical settings (e.g., hospitals, sleep laboratories, sub-acute care institutions) and home environments. It must always be prescribed by a licensed physician.

As compared with the cited predicate device, the Breas iSleep 20i Systems have:

Same intended uses

Same environments of use

Similar design (microprocessor-controlled blower as air source)

Same fundamental scientific technology

The functions that are available in iSleep 20i are also available in the predicate device. The differences that do exist are minimal and involve primarily additional display indicator possibilities in the iSleep 20i system. The features are described in the modified device information section 6 and appendix 6 (draft manuals and sellsheets).

Summary of Performance Testing:

1. Non-clinical testing was conducted to verify that the Breas 20i System is capable of meeting its stated performance specifications and that all Risk Analysis issues have been appropriately addressed. The device passed all applicable tests.

2. Comparative testing to predicate device was performed. This bench testing confirmed that the Breas iSleep 20i System is substantial equivalent when operating in self adjusting "i" mode.

3. Testing was conducted to demonstrate compliance with applicable requirements in the November 1993 draft "Reviewer Guidance for Premarket Notification Submissions" published by the FDA's Division of Cardiovascular, Respiratory, and Neurological Devices and the July 1995 "Draft Reviewer Guidance for Ventilators". The testing included but was not limited to:

- Electrical Safety testing per IEC 60601-1
- Safety and Performance testing per ISO 17510-1
- Electromagnetic Compatibility testing (EMC testing)

- Mechanical Safety testing
- Environmental testing
- Functional testing
- Particle matter testing

The device passed all tests.

4. All device softwares were documented and tested in accordance with the FDA's May 11, 2005 "Guidance for the content of Premarket Submissions for Software Contained in Medical Devices". The device passed all tests.

5. Clinical studies were not required to support a substantial equivalence determination.

Conclusions:

The Breas iSleep 20i System meets its stated performance specifications and criteria outlined in the Reviewer Guidance publications referenced above. We conclude that the device is capable of operating safely in their intended environments and will be effective in fulfilling its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Karl-Jphan Holm
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JAN 2 2 2007

Re: K063476
Trade/Device Name: Breas iSleep 20i System
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: December 22, 2006
Received: December 27, 2006

Dear Mr. Holm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: Breas iSleep 20i System

Indications for Use: The Breas iSleep 20i System is intended to deliver Continuous Positive Airway Pressure (CPAP) therapy for the treatment of adult Obstructive Sleep Apnea (OSA).

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K06 3476

Prescription Use (Per 21 CFR 801.109) X OR Over-the-Counter Use